UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. LE THU, Defendant	Criminal No. 25cr10153 Violations: Counts One and Two: False Statements Relating to Health Care Matters (18 U.S.C. §§ 1035) Forfeiture Allegation: (18 U.S.C. § 982(a)(7))

INFORMATION

At all times relevant to this Information:

General Allegations

1. Defendant LE THU, a resident of Suffolk County, Massachusetts, was a doctor licensed to practice medicine in numerous states, including Massachusetts.

2. Lotus Health Telemed, LLC and Lotus Health Services, LLC (collectively, "Lotus Health") were Florida limited liability companies. Both were telemedicine companies that purported to enable medical providers to access patient records electronically and remotely, and to prescribe medical services to individuals, including genetic tests. The companies worked with marketing companies and medical providers to arrange for medical providers to order, among other things, genetic testing for a purported patient even though medical providers generally did not have contact with the purported patient.

3. RediDoc LLC ("RediDoc") was an Arizona limited liability company. RediDoc was a telemedicine company that purported to enable medical providers to access patient records electronically and remotely, and to prescribe medical services to individuals, including genetic

tests. RediDoc worked with marketing companies and medical providers to arrange for medical providers to order, among other things, genetic testing for a purported patient even though medical providers generally did not have contact with the purported patient.

The Medicare Program

4. The Medicare Program ("Medicare") was a federally funded health insurance program affecting commerce that provided health care benefits to persons who were 65 years of age and older or disabled. The benefits available under Medicare were governed by federal statutes and regulations.

5. Medicare was a "health care benefit program" within the meaning of Title 18, United States Code, Section 24(b) and a "Federal health care program," as defined by Title 42, United States Code, Section 1320a-7b(f).

6. The United States Department of Health and Human Services ("HHS"), through its agency, the Centers for Medicare and Medicaid Services, oversaw and administered Medicare.

7. Individuals who qualified for Medicare benefits were commonly referred to as "beneficiaries." Each beneficiary was given a unique Medicare identification number.

8. Medicare covered, among other things, medical services provided by physicians, medical clinics, laboratories, and other qualified health care providers—including the ordering of diagnostic testing such as genetic testing—that were medically necessary and ordered by licensed medical doctors or other qualified health care providers.

9. Health care providers who provided services to Medicare beneficiaries, including laboratories, were able to apply for and obtain a "provider number." A health care provider who

received a Medicare provider number was able to file claims with Medicare to obtain reimbursement for services provided to beneficiaries.

10. To receive Medicare reimbursement, providers had to apply for and execute a written provider agreement. The provider was required to sign and date the application, and the application contained certifications—under penalty of perjury— that the provider, among other things, agreed to abide by the Medicare laws and regulations, including the Anti-Kickback Statute, and that the provider "will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

11. Medicare-enrolled providers were required to submit claims for services provided to Medicare beneficiaries. 42 U.S.C. 1395w–4(g)(4).

12. Medicare claims were required to be properly documented in accordance with Medicare rules and regulations.

13. Medicare paid for claims only if the items or services were medically reasonable, medically necessary for the treatment or diagnosis of the beneficiary's illness or injury, accurately documented, and actually provided as represented to Medicare. Medicare would not pay for items or services that were procured through kickbacks and/or bribes.

14. When submitting a claim for diagnostic testing, providers were required to set forth, among other information, the beneficiary's name and unique Medicare identification number, the specific type of testing provided to the beneficiary using the appropriate "procedure code," as set forth in the Current Procedural Terminology Manual or the Healthcare Common Procedure Coding

System ("HCPCS"), the date the testing was performed, the amount the provider was billing for the testing, and the name and provider number of the provider who ordered the testing.

Genetic Testing

15. Genetic testing for hereditary cancer used DNA sequencing to detect mutations in genes that could indicate a higher risk of developing certain types of cancers in the future. Pharmacogenetic testing used DNA sequencing to assess how well a patient would likely respond to a specific drug therapy based on the patient's genes. Genetic tests that could predict future risks of cardiac conditions and disease, such as Parkinson's and Alzheimer's, were also available. All such tests were generally referred to as "genetic testing." Genetic testing was not a method of diagnosing whether an individual had a disease, such as cancer, at the time.

16. Medicare did not cover diagnostic testing that was "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Except for certain statutory exceptions, Medicare did not cover "examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint or injury." 42 C.F.R. § 411.15(a)(1). In other words, Medicare generally did not cover tests used for screening purposes. Although there were statutory exceptions that permitted Medicare coverage of certain cancer screening tests such as "screening mammography, colorectal cancer screening tests, screening pelvic exams, [and] prostate cancer screening tests," these statutory exemptions did not include genetic testing.

17. Because genetic testing did not fall within the statutory exceptions pertaining to certain screening tests, Medicare only covered such genetic testing in limited circumstances. For example, for cancer genetic testing, Medicare's coverage was generally limited to when a

beneficiary had cancer and the beneficiary's treating physician deemed such testing necessary for the beneficiary's treatment of that cancer. Medicare did not cover cancer genetic testing for beneficiaries who did not have cancer or lacked symptoms of cancer.

18. Even when Medicare allowed for reimbursement of diagnostic testing, Medicare imposed additional requirements before covering the testing. 42 C.F.R. § 410.32(a) provided that "All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary."

Overview

19. Around 2005, LE THU enrolled as a Medicare provider, promising to comply with all Medicare rules and regulations, including refraining from violating the federal Anti-Kickback Statute and not causing the submission of false or fraudulent claims. Between 2005 and the end of 2020, LE THU signed multiple other Medicare enrollment forms in which she reiterated those certifications.

20. From in or about March 2017 continuing through in or about November 2020, LE THU knowingly and willfully engaged in a scheme involving a health care benefit program, namely, Medicare, to make and use materially false representations, writings, and documents knowing the same to contain materially false, fictitious, and fraudulent statements and entries in connection with the delivery of or payment for health care benefits, items, and services, namely genetic testing for Medicare beneficiaries. LE THU signed and/or caused other individuals who

had no medical training to sign medical documentation, including orders (collectively, "doctors' orders"), for genetic testing for Medicare beneficiaries that made it appear that LE THU was providing legitimate consultations to these beneficiaries, exercising her medical judgment in approving doctors' orders, and approving the orders consistent with medical standards.

21. In fact, these doctors' orders were based on false documentation and not LE THU's medical decision-making. Moreover, the genetic testing was generally not covered by Medicare. Medicare would have denied these claims had it known, for example, that the doctors' orders contained falsehoods, that LE THU signed many of the doctors' orders without reading them or that LE THU had other individuals with no medical training signing the orders on her behalf without LE THU providing any medical services, or that the claims were not the result of a legitimate consultation between LE THU and each beneficiary.

22. LE THU obtained the doctors' orders through multiple telemedicine companies, including, among others, Lotus Health and RediDoc.

23. LE THU hired Robin Darnell to review and sign doctor's orders on LE THU's behalf even though LE THU knew Darnell did not have medical training. Darnell's employees also did not have medical training.

24. LE THU signed or caused doctor's orders to be signed (a) even though LE THU did not see, speak to, or otherwise communicate with or examine the Medicare beneficiaries; (b) without regard to whether the beneficiaries needed the genetic testing; (c) often without reading the doctors' orders; and/or (d) that falsely certified or represented that she had consulted with beneficiaries, conducted examinations prior to ordering genetic testing, obtained consent, and/or would use the testing results to treat the beneficiaries. In signing orders under these circumstances,

LE THU falsified material facts and made false representations or used materially false writings or documents knowing they contained materially false statements that in connection with genetic testing.

25. On or about July 10, 2019, LE THU signed doctor's orders for genetic testing for Patient 1, a Massachusetts-based Medicare beneficiary for which Medicare was billed approximately $5,368.44 and paid approximately $2,886.05. The doctor's orders stated, among other things, that the test results would "assist [LE THU] in making patient-specific clinical decisions" and would "directly impact [LE THU's] patient's medical management."

26. On or about July 30, 2019, LE THU signed doctor's orders for genetic testing for Patient 2, another Massachusetts-based Medicare beneficiary, for which Medicare was billed approximately $24,052.06 and paid approximately $7,748.29. The doctor's orders stated, among other things, that the test results "will determine this patient's medical management and treatment decision."

27. Over the relevant period, LE THU caused laboratories to submit approximately $35.3 million in claims to Medicare based on doctors' orders containing materially false representations, for which Medicare paid approximately $25.3 million, including the claims underlying Counts One and Two.

COUNTS ONE AND TWO
False Statements Relating to Health Care Matters
(18 U.S.C. §§ 1035(a)(2))

The United States further charges:

28. The United States re-alleges and incorporates by reference paragraphs 1-27 of this Information.

29. On or about the dates specified below, in the District of Massachusetts and elsewhere, the defendant,

LE THU,

in a matter involving a health care benefit program, specifically Medicare, as defined in 18 U.S.C. § 24(b), did knowingly and willfully make materially false, fictitious, and fraudulent statements and representations, and make and use materially false writings and documents, knowing the same to contain materially false, fictitious, and fraudulent statements and entries, in connection with the delivery of and payment for health care benefits, items, and services, that is, THU submitted orders for genetic testing, stating the genetic testing would assist THU in medical decision making and/or medical management, when in fact THU had no contact with the beneficiaries and did not intend to and did not provide medical treatment to the beneficiaries based on the genetic testing that she ordered:

Count	Approximate Date	Medicare Beneficiary	Record Containing False Statements and/or Concealment of Material Facts
1	7/10/2019	Patient 1	Written order for genetic testing
2	7/30/2019	Patient 2	Written order for genetic testing

Each in violation of Title 18, United States Code, Sections 1035(a)(2).

FORFEITURE ALLEGATION
(18 U.S.C. § 982(a)(7))

The United States further alleges:

30. Upon conviction of one or more of the offenses in violation of Title 18, United States Code, Section 1035, set forth in Counts One and Two, the defendant,

LE THU,

shall forfeit to the United States, pursuant to Title 18, United States Code, Section 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense. The property to be forfeited includes, but is not limited to, the following asset:

a. $209,755 in United States currency, to be entered in the form of a forfeiture money judgment.

31. If any of the property described in Paragraph 30, above, as being forfeitable pursuant to Title 18, United States Code, Section 982(a)(7), as a result of any act or omission of the defendant—

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intention of the United States, pursuant to Title 28, United States Code, Section 982(b), incorporating Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant up to the value of the property described in Paragraph 30 above.

All pursuant to Title 18, United States Code, Section 982(a)(7).

LEAH B. FOLEY
United States Attorney

By: */s/ Howard Locker*
HOWARD LOCKER
Assistant U.S. Attorney

Date: April 25, 2025